## AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application.

**LISTING OF CLAIMS**

1.-33. (cancelled)

34. (new) A purified and isolated peptide, pE2, consisting of an amino acid sequence identified by SEQ ID NO: 2, homodimers or derivatives thereof having extensions, substitutions, insertions and/or deletions of the amino acid sequences defined by SEQ ID NO:2 provided that they preserve immunochemical reactivity to HEV antibodies as pE2 homodimers.

35. (new) A recombinant fusion protein comprising a heterologous amino acid sequence fused to the peptide pE2 as defined in Claim 34.

36. (new) A recombinant fusion protein according to Claim 35, characterized in that the heterologous amino acid sequence codes for glutathione S-transferase.

37. (new) A method of generating the pE2 peptide, as defined in Claim 34, either by chemical synthesis or recombinant DNA expression.

38. (new) A purified and isolated nucleic acid molecule, E2 encoding peptide pE2 as defined in claim 34, which consists of a DNA sequence identified by SEQ ID NO: 1, or degenerate sequence or fragment thereof.

39. (new) A purified and isolated nucleic acid molecule according to claim 38, which consists of a DNA sequence which encodes the pE2 peptide, as defined in Claim 34.

40. (new) A vector containing the nucleic acid molecule according to Claim 38, characterized in that the vector is capable of expressing the nucleic acid molecule upon introduction into an appropriate host cell or microorganism.

41. (new) A vector according to Claim 40, characterized in that the vector is a plasmid.

42. (new) A vector according to Claim 40, characterized in that the host cell is a eukaryotic cell.

43. (new) A vector according to Claim 42, characterized in that the eukaryotic cell is E. Coli.

44. (new) A host cell or microorganism transformed with the vector as defined in Claim 40.

45. (new) A method for generating the peptide or protein, as defined in Claim 34, comprising inserting a nucleic acid molecule that encodes the peptide or protein into a vector construct that it is capable of being expressed in an appropriate host cell or microorganism, transforming a host cell or microorganism with the vector construct, culturing the transformed host cell or microorganism, and isolating and purifying the resulting peptide or protein product.

46. (new) A method for producing a purified antibody against the pE2 peptide, as defined in Claim 34, comprising injecting into a non-human mammalian host, an immunologically effective amount of the pE2 peptide, and isolating and purifying the antibody produced.

47. (new) A purified antibody, or fragment thereof, which has been raised against the pE2 peptide, as defined in Claim 34.

48. (new) A vaccine composition for immunizing an individual against infection from hepatitis E virus (HEV) comprising the pE2 peptide, as defined in Claim 34, and a pharmacologically acceptable carrier.

49. (new) A method for immunizing an individual against infection from hepatitis E virus, which comprises steps of administration of a vaccine composition as defined in Claim 46 into subject in need.

50. (new) A method for determining the presence or absence of HEV antibodies in a biological test sample, comprising:

- providing a purified and isolated peptide, pE2 according to claim 34;

- contacting the biological test sample suspected of containing HEV antibodies with said pE2 peptide;

- incubating the resultant mixture under conditions sufficient to allow the formation of an immunological (antibody-antigen) complex; and

- examining the mixture for the presence of such an immunological complex, whereby the formation of the complex indicates the presence of HEV antibodies in the test sample.

51. (new) A method according to Claim 50, characterized in that the biological test sample is human blood, serum or plasma.

52. (new) A method according to Claim 50, characterized in that the presence of the immunological complex is determined following incubation with an indicator reagent under conditions permitting a reaction to occur,

53. (new) A method according to Claim 52, characterized in that the indicator reagent is a mammalian anti-human immunoglobulin attached to an enzyme which reacts with a substrate to form a colored product.

54. (new) A diagnostic test kit for the detection of antibodies to hepatitis E virus (HEV), comprising:

- a purified and isolated peptide, pE2, according to claim 1; and

- an indicator reagent capable of detecting an immunological (antigenantibody) complex which contains said pE2 peptide.

55. (new) A diagnostic test kit according to Claim 54, which

further comprises: - control standards; and
- a specimen diluent and/or washing buffer.

56. (new) A diagnostic test kit according to Claim 54, characterized in that said peptide, pE2, is immobilized to a solid support.

57. (new) A diagnostic test kit according to Claim 56, characterized in that the solid support is the well of a titration microplate.

58. (new) A method for detecting hepatitis E virus (HEV) virus particle, in a biological test sample, comprising:

- providing the purified anti-pE2 antibody, as defined in Claim 14;

- contacting and incubating the anti-pE2 antibody with the biological test sample under conditions which allow the formation of a complex containing the anti-E2 antibody and HEV virus particle; and

- examining the mixture for the presence of such a complex, whereby the formation of the complex indicates the presence of HEV virus particle, in the test sample.

59. (new) A method according to Claim 58, characterized in that the presence of the HEV virus particle captured by the anti-pE2 antibody is determined by extracting viral RNA and applying reverse transcriptase polymerase chain reaction (RT-PCR) thereon.

60. (new) A diagnostic reagent for detecting hepatitis E virus (HEV) analyte in a biological test sample comprising the purified anti-pE2 antibody, as defined in Claim 47.

61. (new) The use of a purified anti-pE2 antibody, as defined in Claim 47, as a diagnostic reagent for the detection of hepatitis E virus (HEV) analyte in a biological test sample.

62. (new) A diagnostic test kit for detecting hepatitis E virus (HEV) analyte in a biological test sample, comprising the diagnostic reagent as defined in Claim 60.

63. (new) A diagnostic test kit according to Claim 64, characterized in that the purified anti-pE2 antibody is immobilized to a solid support.

64. (new) An antigenic determinant, characterized in that the antigenic determinant is capable of being immunologically recognized by HEV antibodies present in serum of a patient afflicted with hepatitis E virus (HEV) and by anti-pE2 antibodies, as defined in Claim 47.

65. (new) A diagnostic reagent for determining the presence or absence of hepatitis E virus (HEV) antibodies in a biological test sample, characterized in that the diagnostic reagent comprises a protein, polypeptide or a peptide having in common with the pE2 peptide, as defined in Claim 34, one or more antigenic determinants capable of being recognized by antibodies raised against the pE2 peptide.

66. (new) A diagnostic test kit for the detection of antibodies to hepatitis E virus (HEV), comprising:

- a purified and isolated peptide, pE2, comprising an amino acid sequence identified by SEQ ID NO: 2, or a homologous sequence, fragment or analog thereof which preserve immunochemical reactivity to HEV as the pE2 homodimer;

- an indicator reagent capable of detecting an immunological (antigen-antibody) complex which contains the pE2 peptide, and at least one of the following:

a) a solid support immobilizing the pE2 peptide; and

b) a well of a titration miroplate containing the pE2 peptide.